FEASIBILITY ASSESSMENT OF PERFORMING SURGERY IN A DEPLOYABLE MEDICAL SYSTEM OPERATING ROOM

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ABSTRACT

FEASIBILITY ASSESSMENT OF PERFORMING SURGERY IN A DEPLOYABLE MEDICAL SYSTEM OPERATING ROOM, by MAJ Lisa Ann Toven, 76 pages.

The purpose of this investigation was to assess the feasibility of performing surgery in a Deployable Medical System (DEPMEDS) operating room versus a fixed facility operating room. The focus of the research was on the implications of utilizing DEPMEDS as a substitute surgical suite. The primary study group consisted of both military and civilian hospitals, that utilized DEPMEDS, military surgical experiences during times of deployment, and military training exercises. The data analysis demonstrated evidence in favor of performing surgical procedures in DEPMEDS, as well as contributing to the training and readiness of medical personnel. Based on the variety of DEPMEDS environments presented in this paper, it is evident that DEPMEDS can enhance the ability of military medical personnel to respond to the ever-changing military medical environment. An attempt should be made to perform definitive surgical care cases in DEPMEDS whenever possible. Tracking the DEPMEDS experience from planning phase to completion is an essential and integral method, which provides an expansion of the Army Medical Department database. With the data provided, DEPMEDS may become more feasible, practical, and effective in all environments.

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LIST OF ABBREVIATIONS

ACH	Army Community Hospital
AMC	Army Medical Center
AMEDD	Army Medical Department
AORN	Association of Operating Room Nurses
CDC	Center for Disease Control
CSH	Combat Support Hospital
DEPMEDS	Deployable Medical Systems
ECU	Environmental Control Units
FM	Field Manual
HEPA	High Efficiency Particulate Air
HVAC	Heating, Ventilation, and Air Conditioning
ICU	Intensive Care Unit
ISO	International Standard Organization
JACHO	Joint Commission on Accreditation of Healthcare Organizations
MASH	Mobile Army Surgical Hospital
MEDCEN	Medical Center
MUST	Medical Unit Self-Contained Transportable
OR	Operating Room
OSHA	Occupational Safety and Health Administration
TEMPER	Tent Expandable Modular Personnel
USAMMA	United States Army Medical Material Agency

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CHAPTER 1

INTRODUCTION

Imagine being the commander of a hospital which is in desperate need of renovations. Your facility is the only trauma center in the area and an entire community depends on it for their health care needs. If the hospital does not make immediate repairs, health care services to the community will cease. This situation is not uncommon and often, a combination of age, design flaws, new hospital regulations, or fire and safety deficiencies dictate the need for extensive renovations. This presents on interesting challenge: How does a hospital provide uninterrupted healthcare to a community during renovations? One option is the utilization of deployable medical systems (DEPMEDS). Although designed for military use in a battlefield environment, the use of military medical equipment (Medical Unit Self-Contained Transportable or Deployable Medical Systems) during hospital renovations is not a new concept and a viable option.

This research will focus on renovations within an operating room suite and the implications of utilizing DEPMEDS or Medical Unit Self-Contained Transportable (MUST) as a substitute surgical suite versus a fixed facility operating room. The investigation will identify potential issues with DEPMEDS use and current practice. The knowledge gained may play a significant role in the provision of safe, quality patient care in the surgical setting. Findings will also be useful for training medical personnel and in creating a competency assessment tool. In addition, the results from this research may directly impact the Fort Leavenworth, Kansas, community as its Munson Army Health Clinic will be considering renovation of its operating rooms in the 2002 to 2003 time

frame. The facility is currently contemplating the use of DEPMEDS as an alternative in order to provide and maintain surgical capability during its facility renovation.

Subordinate Questions

The following subordinate research questions were developed to help guide the study:

1. What are the implications of utilizing DEPMEDS that would affect the standard of patient care?

2. What DEPMEDS characteristics may affect surgical procedures?

3. What training competencies are required for DEPMEDS setup and maintenance?

4. Does performing surgical procedures in DEPMEDS present either population or beneficiary restrictions?

5. What are the legal implications of using DEPMEDS as a substitute surgical suite?

6. Is performing surgery in DEPMEDS cost effective when compared to local healthcare facilities after considering manning, resourcing, maintenance, training, and risk?

This paper begins by discussing current literature on MUST and DEPMEDS within a field setting, during conflicts, as well as within the civilian sector and continues by discussing the research methodology, research model, and results. The thesis will conclude with practical applications of the results, limitations, and future directions of the use of DEPMEDS.

Background

Throughout military history, surgical care has been provided in a variety of settings. These arenas vary from converting barns into surgical suites during the Civil War, to performing surgery on the floors of the jungle during World War II and even to under canvas tents during the Vietnam War. With improvements and advances in technology, also came improvements in medical capabilities and equipment, specifically in the surgical arena.

Significant changes in the methods of performing surgery in a field environment occurred during the Vietnam War. The underlying theme for these changes was to conserve the fighting strength and provide medical care to the soldier in the field as far forward on the battlefield as possible. One such development was the MUST equipment (Braun and Levine 1986, 577). The MUST system was a marked improvement from the past system, in that it provided a viable alternative to performing surgery in an uncontrolled environment. This unit allowed for the comprehensive surgical care of patients directly on the battlefield in an environment that closely replicated a fixed hospital facility (see figure 1).

Figure 1 depicts the Medical Unit Self-contained Transportable (MUST) which can be utilized as an operating room environment. This portable shelter enables the establishment of sanitary conditions required in an operating room environment. MUST hospitals provide a controlled environment and other resources needed for high-quality care.

Figure 1: Medical Unit Self-Contained (MUST)

During the 1980s, the Department of Defense performed an analysis of the potential areas of deployment for the United States military. The results indicated that the United States forces required medical assets that were “mobile, flexible, and functional in all climates” (Naval Report Trip No. 99-2 1999). The development of a system of this nature required standardization to increase interoperability between the United States Army, Navy, and Air Force. The solution was the formation of standardized medical equipment called DEPMEDS. DEPMEDS were first introduced during the Gulf War and offered a far better solution to medical care facilities than solutions of the past century.

This second generation, although not a new concept, took into account the joint standardization needed in all military medical arenas. This new system proved to be excellent as far as joint-similar equipment and interoperability between the services. In addition, the cost saving to the military medical departments as a whole was evident. Thus, the military embraced the use of DEPMEDS and began its fielding during the late 1980s.

Figure 2 depicts a field setup of a DEPMEDS. The tactical expandable shelter is also known as an International Standard Organization (ISO) shelter and is the hard-walled shelter used in DEPMEDS. The ISO shelters that are employed in the system are one-sided expandable (2:1) and two-sided expandable. The ISO shelter located on the left in figure 2 is an operating room shelter. The ISO shelter located on the right of figure 2 is a central material service shelter (2:1) which is used to process and sterilize surgical instruments.

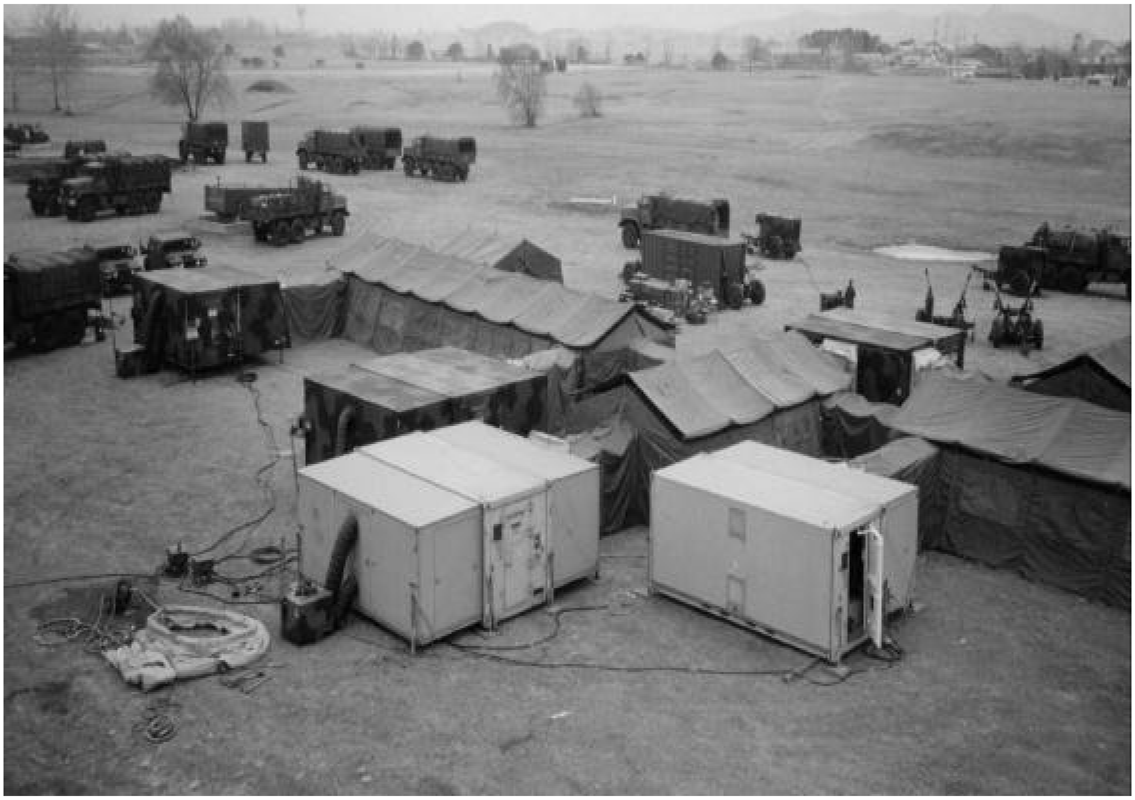

Figure 2: DEPLOYABLE MEDICAL SYSTEMS (DEPMEDS)

Figure 3 depicts a closer view of the DEPMEDS operating room 3:1 box. Note the heating unit which is connected to the operating room. Figure 3 also depicts two operating room ISO boxes which provide the capability of performing four surgical cases simultaneously.

Figure 3: DEPMEDS OPERATING ROOM

Figure 4 depicts the initial expansion of a DEPMEDS ISO box. Note the closed configuration of the operating room ISO box directly above the one being expanded. The shelters are transported in this closed position.

Figure 4: DEPMEDS ISO EXPANSION

Since the 1980s, both MUST units and DEPMEDS have been utilized by both military and civilian medical personnel for a variety of tasks. These tasks include real-world deployments, temporary alternatives during both major and minor hospital renovations, humanitarian missions, as well as responses to natural disasters. In all instances, there were marked advantages and disadvantages to using DEPMEDS. The unique use of deployable medical units will be the focus of this research paper.

In the last five years, hospital renovations have increased by ten percent, and the U.S. Department of Commerce has forecasted a four percent growth in health care construction through the end of 2002 (Joint Commission on Accreditation of Healthcare Organizations, 1999). Many hospital facilities were designed more than thirty years ago.

Due to regulatory changes, technological changes, and facility age, many facilities may require renovation or redesign. Upgrades and renovations are often required within the operating room. The posing thesis question is, How do hospitals renovate while continuing to provide beneficiaries cost-effective, quality surgical care?

With cost constraints and budget cuts, more often than not, hospitals elect to perform major renovations on an existing facility versus building a new facility. This presents formidable challenges in the continuity and continuation of care to health care recipients. To satisfy this need, both the military and civilian sectors have looked at the utilization of DEPMEDS as viable substitutes for fixed facility operating rooms.

Hospitals both military and civilian, have utilized DEPMEDS within the surgical arena. In some cases DEPMEDS have been used as temporary health care facilities while renovations within the hospital were underway. DEPMEDS also have an extensive history of deployment into hostile conflicts and missions other than war. In addition, DEPMEDS have been utilized as a training aid to increase the readiness status of military medical personnel. In these situations, DEPMEDS have provided a practical surgical environment enabling flexibility in surgical care delivery.

Several civilian and military hospitals have utilized DEPMEDS in a variety of different environments successfully, but many challenges were apparent after reviewing the literature. These projects have provided learning experiences with the potential of leading to improvements in medical readiness. The underlying fundamental issue is the delivery of surgical care in an environment that does not compromise quality.

As much of the research has determined, there are many alternatives which can be addressed and evaluated and compared. They are:

1. Sending the patients to other local civilian facilities for surgery
2. Utilizing the surgical suites from the nearest veteran's hospital
3. Sending the patients to another military hospital
4. Renting prefabricated mobile operating rooms
5. Renting space at a nearby neighboring hospital
6. Utilizing DEPMEDS-equipped operating rooms

The ultimate goal of each alternative is to provide continuous, cost-effective surgical care. If the hospital elects to use DEPMEDS, it assumes certain risks associated with providing operative services within DEPMEDS as compared to a fixed facility. Many hospital administrators and staff may scrutinize the operation. The initial challenge is to identify the critical processes of performing surgery within DEPMEDS. Since the main purpose of a hospital is to improve the health of its patients, the operating room is essential to this process. Focusing on the continuity of care and access to the recipients during renovation should be one important level for utilizing DEPMEDS as a hospital service alternative.

The objective of this research is to identify whether the DEPMEDS operating room is a feasible substitute during fixed facility operating room renovation. Certain themes and issues have come to fruition throughout the research process which addresses guidelines and policy. Throughout the use of DEPMEDS in a variety of different scenarios and environments, positive performance attributes of DEPMEDS can be identified and reinforced. Similarly, negative performance attributes can be addressed and improved. It is from this examination that the subordinate research questions evolved.

Assumptions

The following is a list of basic assumptions:

1. Deployable Medical Systems will continue to be the primary medical system utilized by the Armed Forces during deployments.

2. Patient care standards do not deviate or vary when performing surgical procedures within a MUST operating room environment or DEPMEDS operating room environment.

3. MUST units will be utilized by allied medical forces; therefore, there is a potential of U.S. medical personnel performing patient care within MUST.

Limitations

The management of information is not a new concept and has been around as long as health care records. It has become quite evident that the management and gathering of information on DEPMEDS has been an area to which many military medical units have not contributed. Management of the information after training or deployments is a concept which has recently been viewed as critical for the AMEDD. Lessons learned during and at the conclusion of military medical exercises, if properly managed, should lead to improved communication and understanding throughout the medical community. It is the timely management and proper documentation that has been lagging behind and thus has become a limitation to this research.

Definitions

Air Exchange: Total air changes per hour per operating room (American Association of Operating Room Nurses (AORN) 2001).

Definitive Surgical Care: The surgical treatment required to return a service member to health from a state of injury or illness (Field Manual (FM) 8-10-2 2000).

Deployable Medical Systems (DEPMEDS): Standardized modular field hospitals that can be pre-positioned in the event of a contingency, national emergency, or war operations. There are a number of different configurations of standard DEPMEDS hospital modules, such as operating rooms, X-ray rooms, laboratories, and wards.

Fixed Medical Treatment Facility: Denotes a facility established for the purpose of providing health service to authorized personnel (Field Manual (FM) 8-10-2 2000). Fixed refers to a structure which cannot be moved.

Normothermia: The normal body temperature range: core temperature of greater than 36 degrees celcius.

Operating Room or Suite: The environment in which the patient's surgical procedure is performed (American Association of Operating Room Nurses (AORN) 2001).

Patient: The generic term applying to a sick, injured, or wounded person who receives medical care or treatment from medically trained personnel (Field Manual (FM) 8-10-2 2000).

Perioperative: Surrounding the operative and other invasive experiences before, during, and after (American Association of Operating Room Nurses (AORN) 2001).

Perioperative Nurse or Operating Room Nurse: A registered nurse who works in an operating room. Responsible for the clinical and technical knowledge of both scrub and circulating duties in the delivery of surgical care.

Room Humidity: Relative humidity measured in the operating room (American Association of Operating Room Nurses (AORN) 2001).

Room Temperature: Ambient air temperature in the operating room (American Association of Operating Room Nurses (AORN) 2001).

Summary

The utilization of military field equipment during hospital renovations is not a new concept. In the past, MUST and DEPMEDS have been used by both military and civilian hospitals during times of renovation, deployments, and training. Current data and research to identify the implications and issues of utilizing DEPMEDS as a substitute surgical suite remain limited in scope and deserve further investigation. This thesis is an attempt to do just that.

CHAPTER 2

LITERATURE REVIEW

When a hospital fixed facility plans either major or minor renovations, the ultimate goal is to provide continuous, cost-effective care. There are a variety of documented alternatives available during surgical suite modernization efforts. Each alternative solution has advantages and disadvantages which require thorough assessment and analysis. This research will focus on a feasibility assessment of performing surgery in a deployable medical system operating room versus within a fixed facility operating room.

The literature review will include all resources that yield information regarding surgical procedures in MUST and DEPMEDS, operating room training events, deployments, and civilian use of DEPMEDS equipment. A preliminary literature review was conducted of published documents. It provided limited information that specifically addressed the use of MUST and DEPMEDS operating rooms as a substitute during hospital renovation. A follow-up review was conducted which provided a significant number of sources that address issues related to the research question.

The primary means of data collection will be from historically written documents. Data was also derived from interviews of individuals who have utilized DEPMEDS operating rooms. They included personnel from the Army, the Navy, the Air Force, as well as civilians.

The grounded theory and practices of performing surgical procedures in an operating room suite is determined from the *Association of Operating Room Nurses Standard Practices*. In addition, the *Joint Accreditation Committee of Hospital*

Organizations and the *Occupational Safety and Health Administration standards* were referenced and the compliance of these policies. Pertinent data was also collected from the Department of Defense Medical Standardization Board, the Army DEPMEDS Program Manager, the defense logistics agent, the Joint Medical Database, *Armed Forces Standard Operating Procedures*, Department of Defense Office of the Inspector General, the Naval Health Research Center, the Joint Readiness Clinical Advisory Board, the DEPMEDS Database, the Joint Services Deployable Medical Systems Coordinating Group, and the *Department of Defense Medical Readiness Strategic Plan*.

Within the military medical arena, establishing a centralized DEPMEDS library has not been a priority. Combat support hospitals, mobile surgical hospitals, and forward surgical teams have performed surgical procedures in DEPMEDS since the early 1980s. Traditionally, after-action reviews provide documentation on specific issues that arise which provide both historical data and tools to retrieve valuable information.

MUST and DEPMEDS Projects

The Kenner Army Community Hospital (KACH), Fort Lee, Virginia, starting in February 1986, provided continuous comprehensive surgical care to 550 patients utilizing MUST operating rooms. The benefits of the project included quality surgical care, substantial cost savings to the government and the patients, and invaluable training for personnel involved in the project. The Directorate of Engineering and Housing on the installation installed heated and insulated fresh water pipes, as well as sewage lines from the MUST to the fixed facility hospital. Backup power was installed and connected to the hospital power system. Fuel was provided by the Quartermaster Company via a 5,000-gallon tanker. Unfortunately, severe temperature changes resulted in system

failures, pipes and drugs freezing during the winter months, and heat buildup within the MUST during the summer months. One episode of mild hyperthermia was documented which occurred in a pediatric patient in the first 200 cases. Extreme thunderstorms caused flooding within the facility. Based on the size of the MUST operating room, the environment created a crowded environment, but this did not affect surgical care. Special high efficiency particulate air (HEPA) filters were designed and utilized; two infections were documented in 550 cases. A special surgical permit was obtained, and patients were informed of the environment in which their surgical procedure would occur. Cost savings were approximately one million dollars for the government, and savings for retired patients were twenty-five percent deductible from their hospital and surgical bills, as well as decrease in travel (Braun and Levine 1986, 578).

Early in 1987, Cutler Army Community Hospital (CACH), Fort Devens, Massachusetts, closed both its operating rooms for a total of fifty days and utilized MUST operating rooms during renovations. Installation support was required as follows: Directorate of Engineering and Housing for minor construction, electrical, and water support; logistics for the fabrication of HEPA filters; the Staff Judge Advocate office to provide legal assistance; Public Affairs office to created a positive campaign of community awareness; and fire safety was accomplished through the Fire Department and safety officer. Additional fire extinguishers were required to minimize risk. Commercial electrical service was installed as emergency backup, and a thorough evaluation for safety prior to use was conducted by both the safety officer and biomedical equipment section. In addition, electrical systems and equipment checks were required every eight hours to identify and resolve lighting, temperature, and humidity problems.

Water service was provided from a fire hydrant and required special fabricated pressure reducers. Ramps were constructed to facilitate patient transport. Additional bracing and blocking was required for the additional weight of the X-ray machine. A drainage line was installed for nonhazardous waste from the MUST to the fixed facility. Liquid and solid waste was transported via five-gallon plastic containers for disposal within the hospital for treatment via a waste treatment system. Concerns were raised about the level of carbon monoxide concentrations within the MUST operating room, and continuous monitoring was required. Waste anesthetic resulted in the development of a special exhaust system. As a result, pregnant women were restricted from the surgical suites due to the passive ventilation system. Noise levels were adverse to both the patients and the staff. Noise was also a factor pre-recovery and post-recovery. As a result, ear protection was worn by patients, as well as the staff. In an attempt to reduce the decibels, sound matting was placed around the power units. High temperature and humidity was encountered, and a portable commercial dehumidifier was essential. Insects posed a continuous problem, and frequent spraying and cleanup of the dead insects throughout the unit was required each morning. Physical space hampered efficiency and the maintenance of adequate operational levels of supplies in the unit, as well as the placement of oxygen tanks. Latrine facilities were not immediately available to staff; portable commodes would have alleviated this issue. Augmentation and additional training of both medical personnel and maintenance was required which enhanced the training readiness of all involved. Surgeons displayed an overt reluctance during the first one to two weeks in accepting the capabilities of the MUST. Seventy-two surgical

procedures were performed with only one documented minor postoperative infection. The actual cost savings was approximately twenty thousand dollars.

A synopsis of six renovation projects utilizing DEPMEDS will follow. The DEPMEDS operating rooms were utilized in the facilities between June 1989 and May 1992 (Call and Maloney 1993, 326-333).

1. The Veterans Association hospital in Fresno, California, performed 231 surgical procedures during an eight-month period of renovation. The surgical staff opted to utilize equipment from the fixed facility in order to eliminate the need for training on unfamiliar equipment.

2. The 196th Station Hospital, Supreme Headquarters Allied Powers Europe, Belgium, required upgrades due to critical mechanical weaknesses. During a four-month period, 156 surgical cases were performed within DEPMEDS operating rooms. The temporary facility was erected inside a gymnasium which provided a flat surface for the International Standard Organization (ISO) shelters, as well as a bathroom and a shower facility. In addition, the internal environment provided protection from the elements and temperature and humidity problems were decreased.

3. The St. Croix Civilian Hospital, American Virgin Islands, had planned a major renovation when a hurricane rendered the fixed facility inoperable. Fortunately, the DEPMEDS hospital had been erected several weeks prior and served as a community hospital during the disaster. Initially, DEPMEDS field equipment was utilized, but was replaced as fixed facility equipment became available. Standard one-hundred-kilowatt generators were used to provide electricity. Water was provided via water trucks, but eventually both water and sewage was connected to the island system.

4. During a four-month project, Kimbrough Army Community Hospital, Fort Meade, Maryland, performed 1,074 surgical cases during renovations of the heating, ventilation, and air conditioning (HVAC) system. They also elected to use their own equipment, except for suction machines, sonic cleaners, and sterilizers.

5. The Kwajalein Atoll, Marshall Islands Hospital, required major repairs and renovations. This contractor-operated government hospital utilized DEPMEDS from January 1992 through December 1992. Site selection was an issue due to the limited space of the islands land mass.

6. Tripler Army Medical Center (TAMC), Honolulu, Hawaii, was scheduled to replace its twelve surgical suite floors. Due to the mountainous area of the installation, site selection proved to be a challenge. Between November 1991 and May 1992, approximately 1,200 surgical procedures were performed in DEPMEDS.

Another example of DEPMEDS use during hospital renovations occurred in 1997 at the Veterans Affairs Medical Center in Fresno, California. The goal was to maintain the existing workload while providing cost-effective care. A multidisciplinary task force was formed which examined several alternatives. It was concluded that DEPMEDS would be a viable option. Once the decision was made to utilize DEPMEDS, it was determined that modifications were required involving placement of gas, telephone, and water lines. The Engineering Department addressed these needs. The main areas of concern were as follows: patient comfort, infections, maintenance, and electrical capabilities. A number of challenges were identified while utilizing DEPMEDS operating rooms: the weight of the flouroscopy unit, the weight of the intensive care unit bed, security of medications, air quality, operating room lights drifting, transportation of

patients, design of the scrub sinks, the height of the ceilings, temperature control, and HVAC units. A total of 1,396 procedures were performed in the DEPMEDS, and the benefits were evident: cost savings of $3,426,130, continuity of care, and training of military personnel (Etchells 2001, 32-40).

In addition to the above, the following three civilian hospitals successfully utilized DEPMEDS during renovations: Mahaska County Hospital (Iowa), Spencer Hospital (Iowa), and Veterans Administration Medical Center (Fresno, California 2001). There was only one documented use of DEPMEDS during a deployment (212th Mobile Army Surgical Hospital, Croatia) and two training exercises (Walter Reed and Tripler Army Medical Center) which contained significant data which could be incorporated in this research project.

During the review of MUST and DEPMEDS projects, the standard of care was the focus and two common themes emerged: quality assurance and risk assessment. These two themes were further viewed in terms of clinical implications, as they relate within the operating room. At this juncture in the research process, the clinical implications were divided into two categories: positive implications and negative implications. These clinical implications are important and viable aspects to assist in understanding the research question, as well as the subordinate questions.

Positive Implications

1. Efficient use of resources and cost savings
2. Enhanced training and sustainment of health care personnel
3. Enhanced medical readiness
4. Increased opportunity for active duty and reserves to interface in wartime roles

5. Teamwork among all participants

6. Allows soldiers to see the health care they would receive in theater

7. Follows specific training guidance (military medical skills)

8. Source of continuing education

9. Civilian counterpart enhancement and community

10. Minimal disruption to surgical caseload

11. Air condition unit and heat unit can be used all year around

12. The Army has at least two ventilation systems designed specifically to filter

<u>Negative Implications</u>

1. Humidity control

2. Environmental control and temperature

3. Field generators may fluctuate

4. Availability of utilities (water and electricity)

5. Power generation team education

6. Power failure

7. Limited storage capability

8. Communications

9. Infection control

10. Safety hazards, hazardous material, and fire

11. Anesthetic waste and no scavenger system

12. Air circulation and filtration

13. Electrical differences (amps)

14. Significant warm-up time for air-conditioning units

15. Distance of air conditioning unit to operating room table

16. Safety hazards expanding DEPMEDS

17. Unfamiliar with field equipment in the operating room.

18. Proper identification of when to use air-conditioning unit versus heater

19. Water distribution system incorrectly hooked up (waste water to clean)

20. Scrub sinks required significant time to prime

21. Temper tents leak during rain fall

22. Cable connections not tight: leaks

23. Smell from the heaters directly into operating room

24. Operating room table a hazard if not filled with water in base

25. Noise (hearing monitors and blood pressure)

26. Patients prone to hypothermia (no specific equipment)

27. Low ceiling prohibits some X-ray equipment: schedule only certain cases

28. Limitations to certain surgical procedures

29. Heating inconsistent (too hot or too cold): climate control

<u>Concerns</u>

The following concerns were noted:

1. Environmental controls are difficult to maintain in optimal range.

2. Noise levels both inside and outside MUST and DEPMEDS were adverse to both patients and staff.

3. Competency level of DEPMEDS training varied, as well as skills.

4. Modifications were required in most cases of DEPMEDS use during renovations.

DEPMEDS operating rooms are currently being utilized in both Bosnia and Kosovo and have been for several years. Unfortunately, data and documentation for these areas are almost nonexistent. In addition, lesson learned perspective is presented as the initial reference and resource data. Due to the nature of the information, often chronology of data is difficult to determine. In many instances, sources were not properly documented, and the reliability of the source cannot be determined. Finally, some of the data collected from interviews may be subjective and may contain inherent biases.

CHAPTER 3

RESEARCH METHODOLOGY

Data throughout the research process was collected in a variety of different ways. An initial literature review was performed which reveled a trail of additional sources on the subject of DEPMEDS. The Army Medical Department in San Antonio, Texas, was contacted and provided additional insight into points of contact and subject matter experts. An attempt was made to contact the 399th General Hospital recently returned from a deployment in Kosovo. Data was also derived from interviews of individuals who have utilized DEPMEDS operating rooms. They included personnel from the Army, the Navy, the Air Force, as well as civilians. The primary means of data collection was from written documents. This database provided the bulk of the material required for this research project.

A wide variety of techniques can be used to answer research questions. The most common techniques include experimentation, correlation studies, case studies, observation studies, archival research, and grounded research. These techniques can further be divided into qualitative research and quantitative research methods. Qualitative research methods reflect an inductive mode of analysis or a process of moving from a specific observation to a general theory (Norwood 2000, 382-385). This mode of analysis is in contrast to quantitative methods which rely on deductive thinking from a general theory to specific observations. For this research project, grounded theory was utilized as the mode of inductive analysis.

Grounded theory data was collected by observation, by recording, by examining written documentation and literature, and by obtaining perspectives from various

personnel. During data collection, data was analyzed concurrently, and the researcher searched for core variables. The core values have some of the following characteristics:

1. Recur frequently
2. Link various data
3. Have an explanatory function
4. Have implications for formal theory
5. Become more detailed, and
6. Permit maximum variation (Streubert and Carpenter 1999, 117-143).

Data within this framework was coded at three levels. At level one, the data was examined line by line. At the second level, the data was compared and contrasted, and categories or clusters were created. At the third level, movement from data analysis to concept development was achieved. Within this framework, the data was collected in an attempt to ensure saturation, and the data cutoff date was set for 15 February 2002.

The results of level three developments were then categorized into specific implications of utilizing MUST and DEPMEDS operating rooms as a substitute for a fixed facility surgical suite. In addition to the grounded theory analysis, this document assessed the feasibility of using DEPMEDS operating rooms as a viable substitute of a fixed facility operating room. The study examined the feasibility in terms of alternatives and implications.

This retrospective historical review yielded fourteen hospital utilizations of MUST and DEPMEDS. The context of use was as follows: during hospital renovation, during deployments, and during training exercises. Several measures of criteria were then identified which fell under the concept of quality assurance and risk management.

Criteria included the following: noise exposure, nosocomial infections, environmental controls, air exchanges, and electrical capability. The next chapter is dedicated to the analysis of the criteria and its interpretation.

CHAPTER 4

INTERPRETATION AND ANALYSIS OF DATA

The DEPMEDS and MUST operating room modules have been used innovatively to provide assistance to fixed facilities (Call and Maloney 1993, 326-333). Others have been deployed to real-world noncombat scenarios, such as humanitarian missions (Sharp 1994, 386-390). This document makes no distinction between surgical care delivered in such settings. This study was an effort to determine the feasibility of utilizing DEPMEDS operating rooms as a substitute surgical suite during hospital renovations. The focus of the research was on the implications of utilizing DEPMEDS during surgical intervention. The primary study groups consisted of both military and civilian hospitals that utilized DEPMEDS and MUST operating rooms, military surgical experiences during times of deployment, and military training exercises. In all examples, the goal was to provide quality care without compromising standards.

This research differs from preceding analysis in several ways. First, it included both military and civilian experiences in DEPMEDS usage. Second, the research included a variety of environments: garrison, training, and deployments. As a result, the analysis is likely to be generalized to a wider audience and in its consistency of measurement. Finally, an attempt was made to identify causality with regard to the specific clinical implication (positive and negative) and to reduce or negate negative risk factors when utilizing DEPMEDS.

The data that has been collected on the utilization of DEPMEDS and MUST will be analyzed in this chapter. The results of this research are important because both military and civilian hospitals are subject to deterioration, safety deficiencies, and

upgrades; and renovations are often required. The comparison analysis identified quality assurance and risk assessment as the major underlining themes. This was further viewed in terms of clinical implications as they relate within the operating room. The clinical implications will be used as the criteria for the analysis of data. They include the following: noise exposure, nosocomial infections, environmental controls, air exchanges, and electrical capability.

Criteria Defined

Quality assurance is not unfamiliar to medical personnel. It is the purpose and responsibility of health care professionals to protect the patient by assuring quality health care. Quality assurance focuses decision making and health outcomes towards the improvement of health care. In addition, it enhances professional responsibility and the capacity for improving patient care through clinical practice.

Risk management involves the identification of problems and the critical analysis, mitigation, or resolution of these problems. It is the responsibility of health care professionals to control hazards or reduce their risk, especially in the operating room. Health care professionals are responsible and accountable for assessing their environment as a total system and for ensuring that planning, risk management decisions, and execution proactively identifies hazards, assesses the associated risks, and identifies control measures necessary to reduce the risks to the patient (FM 100-14, 1998).

Knowledge of risk factors before patient care and surgical procedures may allow for targeted prevention measures. This knowledge encompasses both quality assurance and risk management and the clinical implications as they relate to both. The following is a list and definition of the criteria used for data analysis.

Noise Exposure: The amount of noise, measured in decibels, an employee is exposed to in a given period of time. This may not equal or exceed an eight-hour-time-weighted average of eighty-five decibels (OSHA 2001).

Nosocomial Infection: An infection which is acquired in a hospital and is caused by microorganisms which contain or produce toxins and other substances that have the ability to invade a host, produce damage within the host, or survive on or in host tissue. An acceptable infection rate postoperatively is between 1.1 percent to 5.4 percent (Centers for Disease Control and Prevention 1999, 130).

Environmental Control: To directly influence or regulate the parameters of temperature, relative humidity, air movement, and air changes within an operating room (*Webster's Medical Dictionary* 2000).

Air Exchange: The number of times air is transferred within a room. A minimum of about fifteen transfers of filtered air per hour, three (twenty percent) of which must be fresh air (American Institute of Architects 1996, 24). Note: Air exchange is being considered as separate criteria based on the fact that temperature and humidity are directly related to each other.

Electrical Capability: The total amount of electrical current required to run all pieces of equipment within the operating room environment. The source of electricity may be from a generator or other machine.

A Composite of DEPMEDS and MUST Experiences

A comparison analysis was preformed to identify each implication during utilization of DEPMEDS and MUST. The analysis was conducted utilizing six civilian renovation experiences, five military renovation experiences, one deployment, and two

military training exercises. As part of the evaluation, the common clinical implications were used as criteria of measurement. It was identified that these clinical implications fell within the realm of quality assurance and risk assessment. The clinical implications included both positive and negative aspects, specific quality of care issues, and potential resolutions for implications affecting patient care.

Environment Defined

1. Training: To instruct as to make proficient.

2. Deployment: The movement of forces within areas of operations; the positioning of forces into formation for battle; the relocation of forces and materiel to desired areas of operations (FM 101-5-1, 1998).

3. Renovation: To make as good as new, to restore.

The following two tables were utilized to compare and contrast the data collected. Table 1 illustrates the aggregate of both MUST and DEPMEDS usage, to include the year, the number of surgical procedures performed, the duration of usage, the average surgical procedures performed per month, and the type of environment the medical units were used. Table 2 offers a comparative glance of the fourteen hospitals and depicts the measured criteria per utilization.

TABLE 1

SUMMARY OF MUST AND DEPMEDS UTILIZATION

	Year	# Cases	Duration	Avg/ Month	Type Environment
Cutler ACH	1987	72	50 days	43	Renovation
Kenner ACH	1989	550	7 months	79	Renovation
196th Station Hosp.	1989	156	4 months	39	Renovation
VA MEDCEN, CA	1989	231	8 months	29	Renovation
Kimbrough ACH	1990	1,074	4.5 months	239	Renovation
Tripler AMC	1991	1,200	5 months	240	Renovation
Kwajalein Atoll	1992	3,000	12 months	250	Renovation
212th MASH	1992	201	5 months	40	Deployment
Mahaska County	1994	241	4 months	60	Renovation
Spencer Municipal	1996	477	8 months	60	Renovation
VA MEDCEN, CA	1997	389	4 months	97	Renovation
Walter Reed AMC	1999	Unk.	2 weeks	N/A	Training
Tripler AMC	2001	50	18 days	N/A	Training
VA MEDCEN, CA	2001	1,396	14 months	100	Renovation

Note: ACH: Army Community Hospital
MEDCEN: Medical Center
AMC: Army Medical Center
MASH: Mobile Army Surgical Hospital
CSH: Combat Support Hospital

TABLE 2

MEASURED CRITERIA PER UTILIZATION

	Noise Exposure	Nosocomial Infection	Env. Control	Air Exc.	Electrical Capability
Cutler ACH	60-90 dec.	1.3%	Severe	15	MUST
Kenner ACH	Note:issue	0.5%	Severe	25	Commercial
196th Station Hosp.	Unknown	1.9%	Moderate	25	Commercial
VA MEDCEN, CA	70 decib.	Within limit	Moderate	25	Commercial
Kimbrough ACH	70 decib.	Within limit	Moderate	25	DEPMEDS
Tripler AMC	70 decib.	Within limit	Moderate	25	Commercial
Kwajalein Atoll	70 decib.	Within limit	Moderate	25	DEPMEDS
212th MASH	Note:issue	0.5%	Moderate	25	DEPMEDS
Mahaska County	Note:issue	1.2%	Severe	25	Commercial
Spencer Municipal	Note:issue	0.6%	Severe	25	Commercial
VA MEDCEN, CA	Note:issue	None noted	Severe	25	Commercial
Walter Reed AMC	Note:issue	Unknown	Moderate	Unk.	DEPMEDS
Tripler AMC	Note:issue	Unknown	Moderate	Unk.	DEPMEDS
VA MEDCEN, CA	Note:issue	Unknown	Severe	25	Commercial

Note: Environmental control: adjust temperature 5-4 times per day (severe variations)
Environmental control: adjust temperature 3-1 times per day (moderate variations)
Air exchanges measures in exchanges per hour

Noise Exposure

Evidence revealed that a majority of the projects had noted noise levels as being adverse to both staff and patients. Based on Occupational Safety and Health Administration (OSHA) Regulation 1910.95 (occupational noise exposure), an employee's exposure may not equal or exceed an eight-hour-time-weighted average of eighty-five decibels. The military follows the guidelines and regulations of OSHA. In addition, the military hearing conservation program states that soldiers will have an annual hearing test. The DEPMEDS operating room has a significant variation in noise level depending on the location, inside or outside the International Organization for Standardization shelter.

It was noted that of the fourteen cases of DEPMEDS and MUST utilization, all but one noted noise as a significant clinical implication. For the fourteen hospital environments which used DEPMEDS and MUST, only one hospital, Kimbrough Army Community Hospital, Fort Meade, Maryland, collected noise sampling data utilizing sound measurements. The sound level meter, Quest Electronics, was used for the collection of measurements.

Table 3 depicts data collected 23 May 1990 at Kimbrough Army Community Hospital, Fort Meade, Maryland.

TABLE 3

NOISE SAMPLING DATA DEPMEDS OPERATING ROOM

Location/Position	Distance From Source (Feet)	Measured Sound Level (decibels)	Permissible Sound Level (decibels)	Type Of Surgery	Powered Instruments Used
Air Vent	0.83	78.0	85	Gen/Ortho	None
Anesthetist-sitting	4.83	66.5	85	General	None
Anesthetist-sitting	4.83	78.0	85	Ortho	Saw
Anesthetist-sitting	4.83	70.0	85	Ortho	Drill
Surgeon-standing	6.0	64.0	85	General	None
Surgeon-standing	6.0	82.0	85	Ortho	Saw
Surgeon-standing	6.0	76.0	85	Ortho	Drill
Circulating Nurse	12.0	62.5	85	General	None
Circulating Nurse	12.0	75.0	85	Ortho	Saw
Circulating Nurse	12.0	70.0	85	Ortho	Drill
General Area	6.0	65.0	85	General	None

From the data collected, it can be seen that working inside a DEPMEDS operating room environment does not exceed the OSHA permissible noise exposure. It must also be noted that the OSHA regulation states that daily exposure time is eight hours. When

the daily noise exposure is composed of two or more periods of noise, the combined effects must be considered (OSHA 2001). Operating room leaders and managers must take into account the effects of longer periods of exposure and develop a monitoring program. DEPMEDS is just one of the many pieces of equipment which can have auditory implications if appropriate measures are not taken. These measures include appropriate audiometric testing and follow-up and effective coordination of hearing conservation program representatives.

In addition to the above resolutions, consideration of shift duration should be taken into account when making the operating room work schedule. Rotating staff every other day into operating rooms performing procedures with decibel levels lower than the previous day is an option. In addition, breaks throughout the day will decrease the overall daily exposure time. It is also recommended that those individuals who have been designated as part of the DEPMEDS power team will wear hearing protection when adjusting environmental control unit (ECU) temperatures, fueling ECUs or generators, or performing maintenance on such equipment.

Based on the data collected, noise is a significant clinical implication when considering the use of DEPMEDS. An additional observation from the AMEDD lessons learned site noted that the DEPMEDS environment was "too noisy to allow monitoring of blood pressure by auscultation" (AMEDD Lessons Learned 3274). Often during trauma, patients do not have palpable blood pressures and health care providers must take readings by means of oscillometric (noninvasive blood pressure). This example, and the data collected directly reflect the implications which noise can have on patient care, as well as health care providers.

Nosocomial Infection

Nosocomial infection was also a significant concern whether in a fixed facility operating room or a DEPMEDS operating room. Nosocomial infections have been recognized for over a century as a critical problem affecting the quality of health care and a principal source of adverse health care outcomes (Gaynes 1997). In addition, infection rate is often equated with the quality of care that is provided to a patient. The primary objective is to place the patient at no risk for infection while hospitalized.

Although efforts are made to safeguard patients undergoing surgery from postoperative infection, research has shown that an average of 1.1 percent to 5.4 percent of patients may experience a nosocomial infection postoperatively. Infection rates that fall within this range are considered acceptable. Based on the data collected, the infection rate for patients who had surgical procedures performed in DEPMEDS was within the acceptable range. The conclusion was made that there is no significant difference in the infection rate of DEPMEDS versus a fixed facility surgical suite.

There have been several comprehensive research projects that have linked surgical wound infections to several sources of contamination. When utilizing DEPMEDS, one must investigate all the ways and means by which contamination could be minimized. The following is a discussion of potential factors which influence airflow and air exchange within the operating room.

By virtue of design, the DEPMEDS operating room ISO introduces air at the floor. As per the guidelines set forth by the American Institute of Architects, air should be introduced at the ceiling and exhausted near the floor. Although no data has been collected on this topic, this is a significant breach in standard. Based on the observation

during data collection, the nosocomial infection rate is maintained within acceptable parameters. In conclusion, although the vent is at the floor, there is no significant increase in nosocomial infection rates when using DEPMEDS operating rooms.

Nosocomial infections are easily prevented if the hospital and its staff follow well-recognized sanitation and hygiene protocols. *The Guidelines for Prevention of Surgical Infections*, 1999, provides recommendations which can be utilized when determining the policy regarding these practices. For instance, frequent hand washing has been shown to significantly lessen the incidence of nosocomial infections. In addition, improved operating room ventilation, barriers, surgical technique, sterilization methods, and traffic control aid in decreasing nosocomial infection rates.

In two separate cases, DEPMEDS scrub sink usage indicated a significant amount of splashing when in use. This may be a potential cause of contamination to hands by bacteria residue in the drain. In order to alleviate the splashing risk, splashguards were constructed and placed on the DEPMEDS scrub sink. This positive action further decreased the risk of nosocomial infection.

As one can clearly see, DEPMEDS facilities can present unique challenges and opportunities for infection control. Identification of potential infection control issues should be conducted early to determine the potential risk for transmission of microorganisms within the hospital. Early involvement in the process can protect patient safety and improve patient care.

Environmental Controls

Regardless of the situation in which DEPMEDS was utilized, environmental controls were a serious issue involving clinical implications. The parameters for which

an operating room must be maintained are often a challenge when performing surgery in DEPMEDS. All cases examined indicated an issue with at least one of the following: temperature control, humidity control, or air control. The following is a list of acceptable parameters in accordance with the American Institute of Architects.

TABLE 4

PARAMETERS FOR OPERATING ROOM ENVIRONMENT

Temperature	68-73 F, depending on normal ambient temperatures
Relative Humidity	30%-60%
Air Movement	From clean to less clean areas
Air Changes	Minimum 15 total air changes per hour Minimum 3 air changes of outdoor air per hour

Source: (American Institute of Architects 1996)

Also related to the standard of care provided to patients and included is the trend of extreme temperature variations within the expandable shelters. The device which is designed to provide a quality environment is called an environmental control unit (ECU). Virtually all aesthesia impairs thermoregulation within the body. Maintenance of normothermia during surgery on patients is essential. Each DEPMEDS ECU is placed outside the temper and ISO rather than inside. Based on the ambient temperature outside, variations within the surgical suite occur throughout the day. As a result, extreme temperature variations are seen within the surgical suite, and this can have serious implications on patients' thermoregulatory capabilities. Evaluation of data pertaining to this issue can be traced back to initial fielding of ECUs to DEPMEDS. Relatively little change has been made to the unit to compensate for this deficiency. It has become quite

evident that technology has been unable to catch up with required modification and refinements necessary to alleviate the temperature variations.

There needs to be a continuous evaluation process and surveillance of the use of DEPMEDS for surgical procedures. Direct reporting, review of after-action reports, and staff surveys via mail or telephone will prove to be an excellent method to obtain data on DEPMEDS usage. Some of the recommendations are based on a strong theoretical rationale and suggestive evidence in the absence of scientific knowledge. Tracking the DEPMEDS experience from planning phase to completion is an essential and integral method which provides an expansion of the AMEDD database.

Air Exchange

Throughout the data collection process, it was noted that a significant number of the hospitals, regardless of setting, had a genuine concern for appropriate air exchanges and particle counts within the DEPMEDS operating room. Operating rooms within a fixed facility can contain dust, skin cells, lint, and respiratory droplets. Air exchange guidelines for an operating room environment are established by the Centers for Disease Control and Prevention and the American Institute of Architects. Current guidelines are as follows:

TABLE 5

VENTILATION STANDARDS

Standard	Pressure Relationship To Other Areas	Changes of Outdoor Air Per Hour	Total Air Changes Per Hour	All Air Exhausted Outdoor	Filtration Percent
Technical Manual	Positive	5	25	Yes	90-95
Center for Disease Control	Positive	5	15	Yes	N/A
American Institute of Architects	Positive	3	15	Yes	N/A
DEPMEDS Operating Room	Positive	5	15-25	No	N/A

The above guidelines indicate that operating rooms should be maintained at positive pressure which prevents airflow from areas considered less clean to areas considered cleaner. In addition, operating room ventilation systems should produce a minimum of fifteen air changes of filtered air per hour, three (twenty percent) of which must be fresh air (American Institute of Architects 1996, 24). The filtering and recirculating of air should be in accordance with the appropriate filter recommended by the American Institute of Architects. In order to assist in the filtration of air, twelve of the DEPMEDS and MUST experiences utilized a high efficiency particulate air (HEPA) filter. HEPA filters remove particles equal to or greater than 0.3um in diameter with an efficiency of 99.97 percent (American Institute of Architects 1996, 24).

Therefore, installation of HEPA filters is essential in DEPMEDS. In order to utilize HEPA filters with DEPMEDS, a special holder with a filter built in was utilized in several of the experiences. In addition, air sampling was performed to ensure the efficacy of the HEPA filter system. The results indicated that the concentrations were consistent

with a fixed facility environment. In one instance, air samples within the DEPMEDS operating room were more suitable than that of the fixed facility.

It was also noted that in all cases of DEPMEDS utilization, bump doors were used in order to ensure positive pressure was maintained. In two instances, duct tape was used around the seams of the ISO to prevent air flow variations.

Electrical Capability

It was noted that of the fourteen cases of DEPMEDS and MUST utilization, twelve noted electricity capability as a significant clinical implication. The exceptions were facilities which relied strictly on commercial electricity, as its main source and contingency backup source. In addition, with the exception of the training event, all cases required some type of electrical modification in order to accommodate surgical procedures within DEPMEDS.

When utilizing the military source of electricity, a significant concern mentioned in ten of the fourteen examples was the potential of an electrical outage during a surgical procedure. An electrical outage during surgery may occur for several reasons: generator failure or possibly, a generator with low fuel. The solution is not simple for many reasons. First and foremost is patient safety and standard of care. Sudden power outages during a surgical procedure can create a situation of sudden and total darkness in the DEPMEDS operating room. Besides being very stressful, there is a potential to place the patient in harms way depending upon what stage of the surgery the doctor is in and what type of anesthetic the patient is having. In addition, sudden power surges play havoc on electrical equipment in the operating room, and often, certain equipment will require reprogramming.

To assist with potential power outages, a thorough coordinated plan must be considered. A plan to have a dedicated generator backup with trained personnel on hand in the event power does cease should exist. Ensure that every operating room has a minimum of three flashlights (one for anesthesia and two for the circulator). Batteries of correct size must be on hand. In addition, the unit or hospital might want to invest in miners' headlights which run on double AA batteries and can be placed on the surgeons' heads for visualization of the surgical field. The pieces of equipment which may be crucial during a power outage are the electrosurgical unit and suction unit. Depending on the duration of the outage, the electrosurgical unit setting will have to be reset. Suction units in a DEPMEDS contain an internal battery which will provide vacuum during outages. This type of suction unit requires the unit to be plugged in when not in use in order to recharge the internal battery. This may present as an issue if power is not being supplied to the ISO box on a twenty-four-hour basis. As a recommendation, the units can be transported inside the fixed facility for recharging at the end of shift. The suction units can then be transported back to the DEPMEDS operating room prior to the start of first cases each day. The DEPMEDS operating room equipment is also equipped with a manual pump suction unit which can be used as a backup unit if required.

Having a contingency plan in place which has been rehearsed by the staff is essential to maintaining a safe environment in the event of a power outage. In order to provide a safer environment, the Joint Commission on Accreditation of Health Care Organizations (JACHO) recommended testing generators weekly without load conditions and once a month with load conditions if the generators were going to be used as backup power (JACHO 1999). Several of the renovation projects installed commercial electric

service as an emergency backup to the DEPMEDS power boxes. Other projects utilized lines from the fixed facility which provided both main and emergency backup service, thus decreasing the potential cease of power.

As a result of deployments and observations in the field, the U.S. Army Medical Material Agency (USAMMA) has written guidelines and specific instruction for the safe connection of DEPMEDS modules to local utility lines. This option provides a viable alternative to using generators. In addition, it may be necessary to operate from commercial power lines depending on the mission or electrical power failure.

It seems likely that a combination of risk factors specific to patients undergoing a surgical procedure in DEPMEDS can be assessed and decreased. The types of environments monitored, the risk factors assessed, and the findings used may differ. Based on the criteria, DEPMEDS is a viable alternative environment which can be utilized successfully for surgical procedures during renovations.

Subordinate Questions

The implications of utilizing DEPMEDS that would affect standards of care have been addressed to include the characteristics of DEPMEDS which may affect surgery. The type of environments monitored and the risk factors assessed may differ based on personnel reporting. But it seems likely that a combination of risk factors specific to patients undergoing a surgical procedure in DEPMEDS can be assessed and decreased.

Another subordinate question which was raised included the legal implications of performing surgical care within DEPMEDS and are there any beneficiary restrictions. Based on the analysis of the data, one specific legal implication was encountered dealing with specific guidelines when considering patient consent forms. Informed consent

means that the patient has received information about the treatment he or she will receive, including, risks, benefits, alternate treatment, and the environment (DEPMEDS). The patient must consent to have their surgical procedure performed within the environment and should be given the option to decline. The data did not indicate any restrictions on beneficiaries having surgery in DEPMEDS and MUST. When considering utilizing an alternate operating room environment, the Staff Judge Advocate should be consulted to provide legal assistance.

The final subordinate question discussed considers the cost effectiveness of performing surgery in DEPMEDS. Several hospitals documented significant savings when utilizing DEPMEDS and MUST. Unfortunately, many of the hospitals did not perform a cost analysis because the data was not unavailable. To gain a greater understanding of the cost savings, table 6 offers a comparative glance of four hospitals which utilized either MUST or DEPMEDS operating rooms during hospital renovation.

TABLE 6

COST SAVINGS WHEN UTILIZING MUST AND DEPMEDS

Hospital	Cost Savings
Kenner Army Community Hospital (1989)	Approximately $750,000-1,000,000
196th Station Hospital (1989)	Approximately $189,700
VA Medical Center Fresno, CA (1989)	Approximately $3,426,130
Mahaska County Hospital (1994)	Approximately $1,000,000
VA Medical Center Fresno, CA (1997)	Approximately $931,710

Based on the above data, the subordinate question cannot be adequately answered in regards to cost effectiveness and benefit. When considering cost, the following areas must also be used as variables: manning, resourcing, and maintenance. The literature did not indicate whether these variables were used in the calculations of total cost savings. Further economic analysis is required in order to quantify these criteria and perform an analysis.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

For more than fifteen years, Medical Unit Self-contained Transportable (MUST) and Deployable Medical Systems (DEPMEDS) have provided an environment to perform surgical procedures in support of a variety of different circumstances. These instances include support of combat missions, missions other than war, training exercises, and hospital renovations. This research focused on renovations within an operating room suite and the implications of utilizing DEPMEDS as a substitute operating room during renovations in a military or civilian facility.

The key to the use of DEPMEDS is a supportive and safe environment which minimizes risk to patients. There are many factors that need to be assessed when considering the use of DEPMEDS. These include the identification and control of physical, chemical, and environmental risk hazards in addition to training requirements, cost considerations, and legal implications. Environmental and occupational exposure testing and monitoring should be a continuous process throughout the utilization of DEPMEDS operating rooms.

Based on the data and evidence presented, performing surgery in a DEPMEDS operating room during hospital renovations is a feasible and viable option. The analysis supported and demonstrated the feasibility of utilizing DEPMEDS during operating room renovations. The clinical implications specific to patients undergoing a surgical procedure in DEPMEDS can be assessed and minimized. These clinical implications included the following: noise exposure, nosocomial infections, environmental controls, air exchanges, electrical capability. As a result of this research, health care providers

considering the utilization of DEPMEDS for surgical procedures can use the information to assist in identifying and resolving typical issues which may impact on standard of care.

Standard of care is defined as the degree of care a reasonable person would do or avoid in order to prevent an injury to another. In such specialized situations, such as the utilization of DEPMEDS operating room, the professional (e.g., doctor, nurse, technician, or any other person with special training beyond that of the average person) will be held to a standard of care, or a duty, which is measured, not by what the untrained person thinks is reasonable (because the untrained person really has no idea, it is not within their common sense), but instead by what other professionals and peers would do in similar situations.

Recommendations

The following are planning recommendations to reduce negative clinical implications when utilizing DEPMEDS.

1. Describe the DEPMEDS project and its parameters
2. Determine essential tasks
3. Review available assets
4. Determine constraints
5. Conduct a risk assessment
6. Conduct a cost assessment
7. Plan the use of available time
8. Develop and analyze course of action based on the above information
9. Create a synchronization matrix of events and timelines
10. Implement the risk management plans and address issues of concern

11. Acquire adequate training based on current policies, procedures, regulations, and techniques

12. Address marketing and advertising issues within the community

13. Realize limitations, follow training, and use good judgment

Noise Exposure

Noise exposure can be decreased in the DEPMEDS environment by utilizing the "tactical quiet" one-hundred-kilowatt generators. This piece of equipment is currently in the military inventory, but as to date is not a DEPMEDS issue. In addition, placing a baffle system around the generator, which can be made out of a low cost wood, will decrease the noise levels. DEPMEDS noise exposure also includes the following: ECUs, orthopedic equipment, electrocautery units, external noise based on DEPMEDS location, and suction units. Army Preventive Medicine teams have the capability of measuring and calculating noise exposure time length. These measurements can provide military leaders with information necessary which can facilitate appropriate shift scheduling, as well as determination of additional hearing evaluations. Finally, all individuals who work on the power generation team, as well as those individuals who may come in contact with DEPMEDS noise hazard, should wear the appropriate hearing protection when needed.

Nosocomial Infections

In order to reduce the risk of nosocomial infections within a DEPMEDS environment, one must realize that the risk is influenced by characteristics of the patient, the procedure, the personnel, and the environment. Knowledge of these risk factors before surgical procedures may allow for targeted prevention measures. In addition, nosocomial infection rate can be reduced by following infection control practices which

include the following: appropriate sterilization methods with monitoring, appropriate surgical technique, hand washing, traffic control within the operating room suite, limiting the number of personnel moving about the operating room suite, maintaining a sterile field, perform routing cleaning of surfaces after each surgical procedure, wet vacuuming the floor of the operating room with an Environmental Protection Agency approved disinfectant, wearing appropriate surgical attire, and ensuring barrier materials provide proper protection to both patient and health care worker. In addition, each patient should be monitored postoperatively for signs of infection. Although designed to perform two surgical procedures simultaneously, it is recommended to utilize DEPMEDS operating room ISO for one surgical procedure at a time. See figure 5 depicting the use of two operating room tables. Optimum application of these prevention measures should be given full consideration when planning on utilizing DEPMEDS as a substitute surgical suite during renovations.

Figure 5: INTERNAL VIEW OF DEPMEDS OPERATING ROOM

Environmental Control

Measures to control the environmental temperature are essential in order to prevent hypothermia and hyperthermia in patients and employees. The patient's body temperature should be maintained as close normothermic as possible. Maintaining body temperature during surgery has significant impact on patient outcome. Temperature control within the DEPMEDS ISO boxes has been a significant issue since inception. It is recommended that the DEPMEDS ESU design be reworked in order to allow temperature control from inside the operating room. Additionally, the operator of the ECU should have the ability to adjust the temperature by incremental degree. In addition, ECU's cannot control the humidity within an operating room environment. It is

recommended that dehumidifiers be part of the equipment in a DEPMEDS operating room. Currently, DEPMEDS do not have a mechanism which will allow the measurement of temperature or humidity. Accurate measurements of these parameters will allow the preemptive adjustment of room temperatures in order to prevent severe temperature swings. An option is the installation of a wall device which accurately measures both temperature and humidity. Ideally, an industrial humidity and temperature transmitter which provides accurate humidity measurements in environments with extreme temperature variations would be best. Industrial humidity and temperature transmitter are currently used in fixed facilities. In addition, there are devices on the local economy which accurately temperature compensate the relative humidity over operating temperature range. This information would provide the operating room staff the exact temperature adjustment required to achieve the ideal environmental conditions within the operating room.

Air Exchanges

A minimum of fifteen air exchanges per hour within the operating room is essential. In addition, maintaining positive pressure ventilation will prevent airflow from less clean areas into more clean areas. Bump through doors must be in place and maintained in the close position in order for the maintenance of positive pressure. It is also recommended that all DEPMEDS ISOs be refitted with HEPA filters and holder. Currently, HEPA filters and holders are not an authorized DEPMEDS piece of equipment and must be fabricated and purchased on a case-by-case basis. In order to meet the standard of care as provided in a fixed facility, HEPA filters must be installed. In addition, when performing surgical procedures within a DEPMEDS, air sampling,

filtration quality, ventilation, and number of air exchanges should be monitored in order to ensure patient safety.

Electrical Capability

When considering utilizing DEPMEDS as a substitute operating room suite, it is recommended to operate off of commercial power lines to meet standards similar to that of a fixed facility and decrease the potential for power outages. This will significantly decrease the potential hazards that would affect patient care. An alternate power source should be considered in the planning in the event of a power outage. The alternate source should take into consideration the appropriate amount of wattages required for the illumination of the surgical field, monitoring patients, and equipment associated with electricity.

Legal Implications

The legal implications of practice were considered when performing surgical care in a DEPMEDS operating room environment. Regardless of the environment in which surgery is performed, the surgical staff must know certain basic legal principles. They must understand the standard of care and the effects of protocols, guidelines, and policy and procedure will have within the surgical environment. Additionally, operating room personnel must understand what informed consent is and their individual role in this process.

In order to understand the standard of care, how it applies in DEPMEDS, and what constitutes a violation of the standard of care, all operating room personnel, in particularly the perioperative nurse, must have a working knowledge of the basic principles of law. Standard of care has been defined as that minimum level of care which

the ordinary, reasonably prudent nurse, in the same or similar circumstances, would provide (Guido 1998, 42-43). The standard of care is determined by reference to a myriad of sources. Laws, including statutes and regulations; treatises and texts; journals; published standards of nursing practice; and employers' written policies, procedures and standards may be used to establish the standard of care.

The standard of care also may include something as seemingly unimportant as medical equipment brochures and instructions. It is important to understand the proper procedures for using any piece of equipment. Failure to operate equipment as recommended by the manufacturer may cause harm to a patient and expose personnel to liability for negligence. The bottom line is that within a DEPMEDS operating room, it is the operating room staffs duty to provide the degree of care ordinarily exercised by staff practicing under the same or similar conditions within a fixed facility. A recommendation is to maintain a copy of all pertinent manuals which deal with standard of care and DEPMEDS.

Health care providers require training in basic legal principles and pertinent state and federal laws if they are to meet the standard of care. The operating room staff must know the policies of the employing institution and be aware of the federal regulations, such as the Joint Commission on Accreditation of Health Care Organizations. These regulations exist to protect and benefit the health, safety, and welfare of patients. Protocols are plans that specify the accepted procedures to be followed in a treatment, examination, or research. Guidelines usually delineate parameters or a range of acceptable behaviors/actions. State and federal legislation provide dynamic components to practice in all settings. Operating room staffs are advised to continue to concentrate

their attention on protecting their patients utilizing the above stated sources of regulations and policies.

Most states have laws regarding informed consent and the requirements for informed consent vary among the states. Some states specify what information must be disclosed to patients and others set forth special forms for obtaining informed consent. Additionally, states vary in how they determine what information is considered to be pertinent to a treatment decision. In general, informed consent requires that the patient be provided with and be able to sufficiently understand information to make a decision regarding medical treatment (Wing, Jacobs, and Kuszler 1998, 105). This includes the environment in which the surgery will be performed. Therefore, there is a legal requirement to consider when implementing DEPMEDS operating rooms.

Consulting legal advice prior to the utilization of DEPMEDS operating rooms as a substitute environment will alleviate legal implications or issues which may arise. Within this special environment may come the need to know other, more specific laws pertinent to the area of practice. As previously stated, this may be state specific. Legal representatives can assist by providing advice and counsel on a broad range of business and legal issues relating to surgical environments and medical care. It is best to seek the advice of a health care law attorney for specific information regarding DEPMED use.

Cost Savings

Today's health care climate mandates that medical professionals carefully examine the cost-effectiveness of decisions, this includes the decision to utilize DEPMEDS during hospital renovations. Based on the data collected, five facilities reported cost savings during the utilization of MUST and DEPMEDS. The criteria for

which the facilities used were not indicated. The assumption can be made that alternate courses of action were evaluated and considered prior to the decision to utilize DEPMEDS. When evaluating cost saving during the DEPMEDS use, consideration must be given to the following:

1. Daily allocated hours of operating room time
2. Estimated hours of surgical cases
3. Actual hours of surgical cases
4. Hours of turnover time
5. Hours of underutilized time
6. Transportation requirements and cost
7. Setup cost of DEPMEDS
8. Maintenance costs
9. Labor pay
10. Payroll savings
11. Site preparation costs
12. Modification cost (equipment, systems, electric, water, phone, and sewage)
13. Marketing cost
14. Training cost

The relationship among these variables may require a statistical analysis in order to determine the exact cost savings of a DEPMEDS project.

Standard Operating Procedures

When considering the use of DEPMEDS during times of renovation, well-defined policies should be in place which are specific to risk factors associated with DEPMEDS.

The developers of these policies and procedures should use current recommended practices which apply as guidelines. These policies and procedures will also assist in the development of risk assessment tools and assist with quality assurance.

Training and Readiness

Military medical readiness is founded on training. Unique training is required when planning, complexing, employing, and utilizing DEPMEDS-equipped surgical suites. This training not only includes medicine, but the equipment medical personnel will see on deployments. The training challenge within the medical community is evident. Baseline competencies and familiarity with medical platforms, supplies, and equipment are key to readiness. To accommodate the use of DEPMEDS, hospital personnel may require additional training.

Readiness training should include the following:

1. Hands-on medical training for medical personnel that is realistic and focuses on the billet and the specific operating room platform

2. Military-civilian training partnership initiatives with focus on military platforms, equipment, and supplies in DEPMEDS

3. Familiarize participants with lessons learned associated with MUST and DEPMEDS use

4. Provide participants with options in training and education which will enable them to make better decisions concerning the utilization of DEPMEDS

With the operational tempo and the uncertainty of medical deployments, trained health care personnel on field equipment are essential. Based on the variety of DEPMEDS environments presented in this paper, it is quite evident that DEPMEDS can

greatly enhance the ability of military medical personnel to respond to the ever-changing military medical environment. An attempt should be made to perform definitive surgical care cases in DEPMEDS whenever possible.

The assessment of MUST and DEPMEDS varied according to the situation used: during deployment, during training, and during renovation. Continuous reassessment during these experiences helps to ensure that deficiencies which can compromise patient care or safety are identified. Direct reporting, review of after-action reports, and staff surveys via mail or telephone can prove to be excellent methods to obtain data on DEPMEDS usage. Unfortunately, a large majority of data from the DEPMEDS experiences has not been forwarded to the appropriate data collection agency within the Army Medical Department. This feedback from the field is essential, and it has become evident that significant data has been lost due to under reporting. In order to counter the adverse outcomes and improve the use of DEPMEDS, the military medical department must perform surveillance and after-action reports to ensure quality and consistency.
In addition, there is a need for objective data regarding the use of DEPMEDS with cross-referencing between all medical services in the military. Gathering data, after the use of DEPMEDS operating rooms, using open ended questions would be useful in that the information may give a more complete picture of areas which require improvement or modifications.

Areas for Further Research

Specific questions have arisen from the analyses which warrant further investigation. These questions are important and need to be answered in view of the way

doctrine and the Army Medical Department missions are unfolding. Follow-up research and issues include the following questions:

1. When does a Deployable Medical System become a fixed facility (e.g., Honduras, Bosnia, Kosovo, and Macedonia)? In all of these instances, construction of a fixed hospital facility was done around the DEPMEDS operating room ISO box. Research has indicated that DEPMEDS operating room ISOs are still currently being utilized and have not been replaced. This raises still another question involving the life expectancy of an operating room ISO under these unique environmental conditions.

2. What is the best mechanism to effectively and efficiently report data in order for it to be readily available to all health providers in a timely manner? An excellent resource is the Army's Center for Army Lessons Learned and the Army Medical Department lessons learned site. The Center for Army Lessons Learned and Army Medical Department site collects and analyzes data from a variety of current and historical sources. These sources include Army operations and training events. Both disseminate these lessons and other related research materials through a variety of print and electronic media. Is this the best mechanism for the military medical department, and does it effectively capture the information required at the tactical and strategic level?

3. What, if any, is the benchmark for competency for medical personnel and readiness? Is it feasible to expect the same benchmark for Reserve personnel?

Given the changing health care environment in which medical professionals practice, operating room efficiency, productivity, and cost containment are increasingly vital to survival. One of the greatest challenges facing health care providers is in the improvement of health care services in the face of diminishing resources. When a

hospital makes the decision to utilize DEPMEDS during hospital renovations, patient welfare followed by cost containment should be foremost in the hospital administrative staffs' minds. The subject matter of this thesis expands awareness and understanding of the utilization of MUST and DEPMEDS operating room for surgery. The text of the thesis provides information on technical aspects of utilizing DEPMEDS, as well as legal implications, resourcing issues, cost considerations, risk assessment, and quality assurance.

Continuous quality improvement is another benefit of performing surgical procedures in DEPMEDS. Through ongoing self-evaluation, the military medical department can continually improve the quality of care. By stressing the DEPMEDS strengths and weaknesses and addressing areas in need of further improvement, data-based lessons learned can be created which allow the organization to look at itself in a more critical manner. Utilizing the after-action review process facilitates the efforts to make changes and improve processes and outcomes. This will result in the best practices in the operating room setting, both DEPMEDS and fixed facilities.

In closing, DEPMEDS is a viable alternative environment which can be utilized successfully for surgical procedures during renovations. The primary study group consisted of both military and civilian hospitals, which utilized DEPMEDS, military surgical experiences during times of deployment, and military training exercises. The data presented evidence in favor of performing surgical procedures in DEPMEDS, as well as contributing to the training and readiness of medical personnel. Based on the variety of DEPMEDS environments presented in this paper, it is quite evident that DEPMEDS can greatly enhance the ability of military medical personnel to respond to

the ever-changing military medical environment. Tracking the DEPMEDS experience from planning phase to completion is an essential and integral method, which provides an expansion of the AMEDD database. With this information DEPMEDS may become more feasible, practical, and effective in all environments.

GLOSSARY

Air Exchange: Total air changes per hour per operating room (AORN 2001).

Note: Air exchange is being considered as separate criteria based on the fact that temperature and humidity are directly related to each other.

Air Exchange: The number of times air is transferred within a room. A minimum of about fifteen of filtered air per hour, three (twenty percent) of which must be fresh air (American Institute of Architects 1996, 24).

Definitive Surgical Care: The surgical treatment required to return a service member to health from a state of injury or illness (FM 8-10-2 2000).

Deployable Medical Systems (DEPMEDS): Standardized modular field hospitals that can be pre-positioned in the event of a contingency, national emergency, or war operations. There are a number of different configurations of standard DEPMEDS hospital modules, such as operating rooms, X-ray rooms, laboratories, and wards.

Deployment: The movement of forces within areas of operations; the positioning of forces into formation for battle; the relocation of forces and materiel to desired areas of operations (FM 101-5-1, 1998).

Electrical Capability: The total amount of electrical current required to run all pieces of equipment within the operating room environment. The source of electricity may be from a generator or other machine.

Environmental Control: To directly influence or regulate the parameters of temperature, relative humidity, air movement, and air changes within an operating room (Webster's Medical Dictionary 2000).

Fixed Medical Treatment Facility: Denotes a facility established for the purpose of providing health service to authorized personnel (FM 8-10-2 2000). Fixed refers to a structure which can not be moved.

Noise Exposure: The amount of noise, measured in decibels, an employee is exposed to in a given period of time. This may not equal or exceed an eight-hour-time-weighted average of eighty-five decibels (OSHA 2001).

Normothermia: The normal body temperature range; core temperature of > thirty-six degrees celcius.

Nosocomial Infection: An infection which is acquired in a hospital and is caused by microorganisms which contain or produce toxins and other substances that have the ability to invade a host, produce damage within the host, or survive on or in host tissue. An acceptable infection rate postoperatively is between 1.1 percent to 5.4 percent (Centers for Disease Control and Prevention 1999, 130).

Operating Room or Suite: The environment in which the patient's surgical procedure is performed (AORN 2001).

Patient: The generic term applying to a sick, injured, or wounded person who receives medical care or treatment from medically trained personnel (FM 8-10-2 2000).

Perioperative Nurse or Operating Room Nurse: A registered nurse who works in an operating room. Responsible for the clinical and technical knowledge of both scrub and circulating duties in the delivery of surgical care.

Perioperative: Surrounding the operative and other invasive experiences before, during, and after (AORN 2001).

Renovation: To make as good as new, to restore.

Room Humidity: Relative humidity measured in the operating room (AORN 2001).

Room Temperature: Ambient air temperature in the operating room (AORN 2001).

Training: To instruct as to make proficient.

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